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Application of Simon Erani
Serial No. 09/922,233 filed 8/3/2001
Response of 2/10/2008 to Office Action of 8/10/2007

Remarks

Receipt is acknowledged of the Office Action of August 10, 2007. Reconsideration of the application and an extension to the present date are hereby requested. The Commissioner is hereby authorized to charge Deposit Account No. 50-1604 for all fees required, and it is requested that any overpayments be credited thereto.

In the Office Action, the rejection of claims 19-40 under 35 U.S.C. §112, first paragraph, was maintained as failing to comply with the written description requirement on the grounds that the claim language is not supported by the specification. Reconsideration is respectfully requested.

Claim 19 recites providing a composition comprising MDT-5, wherein MDT-5 consists of: a form of Vitamin A consisting of Retinyl Palmitate Polypeptide, a form of Vitamin C consisting of Ascorbylmethylsilanol Pectinate, a form of Vitamin E consisting of Tocopheryl Polypeptide, a form of Vitamin D consisting of Cholecalciferol Polypeptide, and a form of Vitamin B3 consisting of Niacinamide Polypeptide. The specification expressly discloses this.

For example, Tables 1a and 1b show various embodiments of MDT-5 consisting of five components, namely, Retinyl Palmitate Polypeptide, Ascorbylmethylsilanol Pectinate, Tocopheryl Polypeptide, Cholecalciferol Polypeptide, Niacinamide Polypeptide. See, Tables 1a and 1b, specification at pgs 3-4.

The specification likewise shows that Retinyl Palmitate Polypeptide is a form of Vitamin A known as Vitamin A Polypeptide, that Ascorbylmethylsilanol Pectinate is a form of Vitamin C known as Vitamin C Polypeptide, that Tocopheryl Polypeptide is a form of Vitamin E known as Vitamin E Polypeptide, that Cholecalciferol Polypeptide is a form of Vitamin D known as Vitamin D Polypeptide, and that Niacinamide Polypeptide is a form of Vitamin B3 known as Vitamin B3 Polypeptide. See e.g., Table 4 at page 10.

The specification also states that "the composition includes Retinyl Palmitate Polypeptide, Ascorbylmethylsilanol Pectinate, Tocopheryl Polypeptide, Cholecalciferol Polypeptide, and/or Niacinamide Polypeptide. It is desirable that these particular components are utilized, as opposed

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to other forms of Vitamin A, Vitamin C, etc., due to the fact that they have been found to produce significantly superior results.” See, specification p. 3, lines 3-5 (emphasis added herein).

Thus, every element of the claim is disclosed in the specification.

Similarly, with respect to the comprising and consisting of language of claim 19, as noted above the formulation in Table 4 shows that other compounds are used in conjunction with those five vitamin forms. Thus, the preamble uses the term “comprising” to indicate that the five vitamins can be used with other components, as shown in the specification. But the MDT-5 of claim 19 “consists” of the recited vitamin forms, excluding other forms of those particular vitamins, for each of the five vitamins listed, as per the preferred embodiment discussed on page 3.

The claim is “open” as a whole, but each of the clauses to the recited vitamins use the term “consisting of”, which is a closed term limiting those particular clauses. Such a recitation is a proper one supported by precedent at the Federal Circuit. See e.g., *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 1282 (Fed. Cir. 1986) (“The district court correctly observed that the phrase “consisting of” appears in clause (a), not the preamble of the claim, and thus limits only the element set forth in clause (a). The court correctly declined to read this usage of “consisting of” as excluding all other elements from the claim as a whole.”).

Accordingly, the claim is fully supported by the specification as initially filed. Withdrawal of the rejection is respectfully requested.

With respect to the §103 rejection, reconsideration is requested. The Supreme Court recently stated that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art”. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). In *KSR*, the Court stated that the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation. *Id.* It also warned against overemphasis on the importance of published articles and the explicit content of issued patents. *Id.* Most inventions rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what is already known. *Id.* Also, in many

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fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. *Id.*

While, admittedly, those factors may facilitate a finding of obviousness in a given situation, it is respectfully submitted that they can also facilitate a finding of non-obviousness. Here, with respect to the drive of market demand, millions of dollars are spent on research in this area, yet the evidence shows in a very objective sense that the many researchers patenting in this field did not see fit to proceed in applicant's direction at the time of the invention, or in any direction even comparable. It is submitted that this evidence of the market and market direction is relevant to the obviousness determination under the recent *KSR* decision. *Id.*

This is a field where there are many patents and much prior work on vitamins and skin treatment, but there does not appear to be any evidence that prior researchers have recognized the benefits of combining even one of the four polypeptide components with Ascorbymethylsilanol Pectinate for a skin care product, much less the combination of all five components together which is required by several of the claims (e.g. claims 1 and 19). Nor is there recognition of the benefits of the particular concentrations recited in the claims above. Considering that biochemistry is a relatively unpredictable field, it cannot be said that one can reliably predict the results for a combination of components together for skin care (which is an element required by all the claims, as amended above), or for the necessary concentrations.

Similarly, it is submitted that the absence of references (which was discussed in the Response of May 17, 2007) does have relevance since this is a relatively crowded art. In fact, the Supreme Court itself previously considered and gave weight to this factor in determining whether or not an invention is obvious. See, *United States v. Adams*, 383 U.S. 39, 52 (1966) ("in a crowded art replete with a century and a half of advancement, the Patent Office found not one reference to cite against the Adams application").

Thus, the evidence previously presented, which relates to the approaches of others in the art, is extremely relevant. It demonstrated that Applicant's approach was an uncommon one constituting

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non-obvious invention. Those secondary considerations are relevant to the obvious determination, but were given no weight in the Office Action. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983) (evidence of secondary considerations must be considered on the question of obviousness and may be the most probative evidence in the record). They are all objective indicators that the invention was not obvious to one of ordinary skill in this art at the time it was made, as opposed to speculation regarding combination of references which is very subjective.

Furthermore, no evidence has been provided in the Office Action with respect to claim 19. There is no evidence in the record which would make it obvious to provide a composition which uses the recited forms, and excludes other forms of those vitamins, as required by the "consisting" language in that claim.

With respect to the ratios provided in claims 2 and 20, reconsideration is likewise requested. It is respectfully noted that the position in the Office Action of August 10, 2007 with respect to the ratios directly contradicts the position taken in the prior Office Actions of October 6, 2004 and July 15, 2005. Those prior Office Actions both recognized that these ratios are patentable. Moreover, no evidence has been cited since then disclosing or suggesting these ratios. Accordingly, it is respectfully noted that the subsequent rejections should not have been issued. See, MPEP §706.04 (8th Ed., Rev. 2 May 2004) (great care should be exercised in authorizing rejection of a claim previously noted as allowable).

Furthermore, the rationale in the subsequent Office Actions does not support the rejection. The fact that an answer can be determined by enough experimentation doesn't make the answer obvious. If that were so, then virtually nothing would be patentable. Nearly all scientific discovery is achieved by experimentation.

When Congress enacted §103, it stipulated the very opposite from what is currently being held in the Office Actions. In the second sentence of §103(a) it specifically enacted that "Patentability shall not be negated by the manner in which the invention is made". As set forth in the Revisor's Note, "The second sentence states that patentability as to this requirement is not to

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be negated by the manner in which the invention was made, that is, it is immaterial whether it resulted from long toil and experimentation or from a flash of genius".

The courts have likewise recognized this. "The second sentence of section 103 was intended to abolish the "flash of creative genius" test, *Graham v. John Deere Co.*, 383 U.S. 1, 15, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966), and the Revisor's Note makes this clear beyond doubt". *Ling-Temco-Vought, Inc. v. Kollsman Instrument Corp.*, 372 F.2d 263, 271 (2nd Cir. 1967).

Accordingly, the fact that the result was achieved by experimentation does not affect patentability. It is a specific ratio which is being claimed, and no evidence has been given that that specific ratio is obvious. The manner in which the invention was achieved is immaterial. It is the result which must be evaluated. The result is not at all obvious, and is therefore respectfully patentable. It is respectfully submitted that the same holds true for the specific concentrations recited in claims 15-18 and 29-40 as well.

Accordingly, reconsideration of the rejections and favorable action on the application is respectfully requested.

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Respectfully submitted,



Morris E. Cohen (Reg. No. 39,947)
1122 Coney Island Avenue, Suite 217
Brooklyn, New York 11230
(718) 859-8009 (telephone)
(718) 859-3044 (facsimile)